

Amendments to the Claims

1. (Previously presented) A pharmaceutical composition for transmucosal administration of a bioactive peptide or protein of interest comprising said bioactive peptide or protein of interest, a cationic polyamino acid, and a compatible buffer, wherein at the pH of the composition said compatible buffer does not cause precipitation of the cationic polyamino acid, and has a mono-anionic or neutral net charge; and

wherein the bioactive peptide or protein of interest has the same net charge as the cationic polyamino acid at the pH of the composition; and

wherein the transmucosal absorption of said bioactive peptide or protein is increased relative the absorption of said bioactive peptide or protein in the absence of said cationic polyamino acid.

2. (Original) The composition of claim 1, wherein the pH of said composition is between about pH 4.0 and about pH 6.0.

3. (Original) The composition of claim 1, wherein the pH of said composition is between about pH 4.0 and pH 5.0.

4. (Original) The composition of claim 1, wherein said compatible buffer is selected from the group consisting of acetic acid, ϵ -aminocaproic acid or glutamic acid.

5. (Original) The composition of claim 1, wherein said compatible buffer comprises glutamic acid.

6. (Original) The composition of claim 1, further comprising a tonicifying agent, a viscosity-increasing agent, a bio adhesive agent, a preservative, or any combination thereof.

7. (Original) The composition of claim 1, wherein said cationic polyamino acid comprises poly-histidine, poly-arginine, poly-lysine, or any combination thereof.

8. (Previously presented) The composition of claim 7, wherein said cationic polyamino acid has an average molecular weight of between about 10 kDa and about 200 kDa.

9. (Original) The composition of claim 1, wherein said bioactive peptide or protein is an exendin, an exendin analog, or an exendin derivative.

10. (Original) The composition of claim 1, wherein said bioactive peptide or protein is selected from the group consisting of exendin-3, exendin-4, exendin-4 acid, exendin-4 (1-30), exendin-4 (1-30) amide, exendin-4 (1-28), exendin-4 (1-28) amide, ¹⁴Leu, ²⁵Phe exendin-4 amide, and ¹⁴Leu, ²⁵Phe exendin-4 (1-28) amide.

11-14. (Canceled)

15. (Original) The composition of claim 6, wherein said tonifying agent is selected from the group consisting of sodium chloride, mannitol, sucrose, glucose and any combination thereof.

16. (Original) The composition of claim 6, wherein said viscosity-increasing agent is selected from the group consisting of: hydroxypropyl cellulose, hydroxypropyl methylcellulose, methylcellulose of average molecular weight between about 10 and about 1,500 kDa, starch, gums and any combination thereof.

17. (Original) The composition of claim 6, wherein said bioadhesive agent is selected from the group consisting of: carbomer, polycarbophil and any combination thereof.

18. (Original) The composition of claim 6, wherein said preservative is selected from the group consisting of phenylethyl alcohol, methylparaben, ethylparaben, propylparaben, butylparaben, chiorbutanol, benzoic acid, sorbic acid, phenol, m-cresol, alcohol, and any combination thereof.

19. (Original) The composition of claim 1, wherein said absorption is increased at least 2 fold.

20. (Original) The composition of claim 1, wherein said absorption is increased at least 5 fold.

21. (Original) The composition of claim 1, wherein said absorption is increased at least 10 fold.

22. (Previously presented) A pharmaceutical composition for transmucosal administration of a bioactive peptide or protein of interest comprising about 0.01% to about 5.0% (w/v) of said bioactive peptide or protein of interest; about 0.01% to about 1.0% (w/v) of a cationic polyamino acid having a molecular weight between about 10 kDa and about 200 kDa; and about 0.01% to about 10.0% (w/v) of a compatible buffer, wherein at a pH of between about pH 4.0 and about 5.0, said compatible buffer does not cause precipitation of the cationic polyamino acid and has a mono-anionic or neutral net charge; and wherein the bioactive peptide or protein of interest has the same net charge as the cationic polyamino acid at the pH of the composition, and wherein the transmucosal absorption of said bioactive peptide or protein is increased relative the absorption of said bioactive peptide or protein in the absence of said cationic polyamino acid.

23. (Original) The composition of claim 22, further comprising between about 0.001% to about 10.0% of a tonifying agent.

24. (Original) The composition of claim 22, further comprising between about 0.001% to about 10.0% of a viscosity-increasing agent.

25. (Original) The composition of claim 22, further comprising between about 0.001% to about 10.0% of a bioadhesive agent.

26. (Original) The composition of claim 22, further comprising between about 0.001% to about 10.0% of a preservative.

27. (Previously presented) A pharmaceutical composition for transmucosal administration comprising about 0.5% (w/v) of exendin-4; about 0.5% (w/v) of poly-arginine having an average molecular weight of about 141 kDa; and about 0.56% monosodium glutamate

monohydrate (w/v), at a pH of about 4.5 and wherein the exendin-4 has the same net charge as the poly-arginine at the pH of the composition.

28. (Original) The composition of claim 27, wherein said poly-arginine is poly-L-arginine.

29. (Original) The composition of claim 27, wherein said composition further comprises a tonicifying agent, a viscosity-increasing agent, a bioadhesive agent, a preservative, or any combination thereof.

30. (Original) The composition of claim 27, further comprising about 0.72% sodium chloride (w/v).

31. (Previously presented) A pharmaceutical composition for transmucosal administration comprising about 0.5% (w/v) of exendin-4; about 1.0% (w/v) of poly-arginine having an average molecular weight of about 141 kDa; and about 0.56% monosodium glutamate monohydrate (w/v), at a pH of about 4.5 and wherein the exendin-4 has the same net charge as the poly-arginine at the pH of the composition.

32. (Original) The composition of claim 31, wherein said poly-arginine is poly-L-arginine.

33. (Previously presented) The composition of claims 31, wherein said composition further comprises a tonicifying agent, a viscosity-increasing agent, a bioadhesive agent, a preservative, or any combination thereof.

34. (Original) The composition of claim 31, further comprising about 0.72% sodium chloride (w/v).

35-50. (Canceled)